

66. The apparatus of claim 65 wherein said central detection area consists of optical connections to a detector system.

67. The apparatus of claim 66 wherein said optical connection of said central detection area to said detection system comprises fiber optics.

68. The apparatus of claim 66 wherein said optical connection of said at least two illumination areas and said at least one source of illumination comprises fiber optics.

69 → PLEASE ADD THE FOLLOWING NEW CLAIMS:

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70. The apparatus of claim 67 wherein said central detection area consists of optical fibers which consist of a detection system.

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70. The process of claim 58 wherein said central detection aperture consists of fiber optics which consist of a detection system.

REMARKS CONCERNING THE AMENDMENT

The above amendment to claim 58 was made in an effort to correct an obvious grammatical error. No antecedent basis is needed for this non-substantive amendment to this claim. The above amendment to claim 33 was made in an effort to correct obvious typographical errors.

The above amendments to claims 34 and 42 remove reference to claims 33 and 36 because "...an extended surface area of one of said paths being contained within the boundary defined by an extended surface area of another of said paths and being substantially surrounded by the extended surface area of said another of said paths." (Claims 33 and 36) is inconsistent with "...on opposite surfaces of said material." (Claims 34 and 42). In claim 34, "claim 33" is replaced by the more appropriate "claim 1 or claim 6" paralleling the existing reference to claim 7 in claim 42.

The description added to claims 1 and 7 of a spectrum (i.e., multiple or a series of wavelengths, as defined by "Webster's Seventh New Collegiate Dictionary") from the specimen may be found generally in the specification and, for example, on page 9, lines 9, 14, 16 and 29. The relationship between the analytes and interferences and the spectrum may be found on page 9, lines 8-9. Antecedent basis for combining signals may be found on page 9, line 6. Antecedent basis for chemometric modeling and the calibration process may be found on page 9, lines 33-35, and on page 10, lines 11-13 and 17-18.

Antecedent basis for the amendment to claim 6 may be found generally in the specification and, for example, on page 8, lines 7-10.

The addition of new claims 69 and 70 add claims which requires the optical fibers in the central detection area to exclude the presence of fibers for functions other than detection (e.g., such as illumination), thereby specifically further excluding the system of Borsboom. Antecedent basis for this limitation may be found generally in the specification and, for example, in the Figures and the description of the Figures.

RESPONSE TO THE REJECTION

Claims 1, 6, 7, 33, 34, 36-42 and 56-68 have been rejected under 35 U.S.C. 103(a) as unpatentable over the prior art discussed on pages 2-4 of the specification and Borsboom in view of Howarth and Hirao et al.

The rejection asserts that:

The specification teaches that in the prior art, interaxial measurements are made using a "central aperture surrounded a small distance away by a ring aperture" and a ring aperture would be circular.

Borsboom particularly shows an arrangement with this structure, with a central aperture 2 and a circular ring 7 around the central aperture; especially pointing out Figure 4 of Borsboom.

The ring of the prior art and Borsboom are both "extended in length" and "the total length of said extended surface area being substantially greater than the mean distance separating " the two areas defining the light path through the material.

The arrangement of the prior art in the specification is acknowledged as showing only a single path through the sample, with Borsboom showing light scattered back through the same element (indicating that this is a "second path through the object").

It is then asserted that it is known to measure light passing through a material at two different distances. It is attempted to support this teaching in the Office Action by citation of Hirao et al. and Howarth.

Howarth (Figures 6 and 7) and Hirao et al. (Figures 2 and 4) teach two different path lengths through the material, neither path being directly back.

It is then asserted as a legal conclusion that it would have been obvious to provide means (as in Howarth and Hirao et al.) to measure two different distances through the material because the art recognizes that this is useful.

It is asserted that this effect would have been performed by adding a second ring at the desired second distance, especially as Borsboom suggest a plurality of rings (e.g., column 3, line 61 through column 4, line 1).

It is asserted that Hirao et al. teaches that two different length light paths can be obtained with one detector and two light sources (Figure 2) or one light source and two detectors (Figure 4).

It is asserted that Howarth shows placing the light detector or transmitter at an angle to direct the light toward, or detect the light from, the other end of the light path.

It is asserted that Hirao et al. shows it is a known technique to place the illumination and the receivers on opposite sides of the object.

It is then asserted as a legal conclusion that other arrangements than concentric circles for the illumination and detection areas would be obvious because it is the transmission of light through the material, and not the particular geometry of the light source and detectors, that is of functional importance.

This rejection is respectfully traversed. This traversal will include arguments directly on the failure of the merits of the rejection and by removal of the Hirao et al. reference as prior art by a declaration under 37 C.F.R. 1.131.

Patentability of Claims 56-63

It is critical to an understanding of the failure of the rejection to appreciate the following specific facts:

As accepted by the Examiner, Borsboom does not have two rings of fibers defining two different path lengths for the light to travel, and all reflectance which Borsboom intends to observe from opaque materials travels as reflection through the same optical element.

What was not appreciated was that, even where Borsboom has been quoted in the Office Action as teaching concentric distributions of optical fibers, that teaching is clearly and unequivocally directed towards only a distribution of light collecting fibers surrounding light emitting fibers. This is absolutely clear because in the quoted portion of the reference it is stated that

“Measurements made with such a sensor head give a good picture of the amount of reflected light *that has entered the fibers arranged concentrically in rings...*”

The only distribution of fibers shown by Borsboom is, at best, a distribution of collector optics surrounding a core of both emitters and collectors (See Figure 4 as well as the quoted text). Claim 56 requires

“a distribution of substantially equidistant illumination means surrounding a central detection area...”

To render the structure of claim 56 obvious from the teachings of Borsboom, it would have to be shown that the light emitting optical fibers must be moved to the surrounding circumference of the sensor head. That is not specifically suggested or taught in any reference. Borsboom does not teach the surrounding of a core of receptors with concentric circles of emitters, and neither do the teachings in the specification of Howarth or Hirao et al. There is no basis from the teachings of any reference in the rejection to place emitters circumferentially distributed around the collectors. Claim 56, and all claims dependent therefrom are *prima facie* unobvious since there is absolutely no evidentiary basis for making the assertion that one of ordinary skill in the art has been taught to put emitters circumferentially around a receptor. At a minimum, this is the opposite of what is shown by Borsboom. The fact that the specification clearly supports

a teaching of better results by this distribution of emitters and collectors, strengthens the fact that there is a failure in the teachings of the references in this rejection.

Claim 57 also restricts the optical fibers in the core of the sensor head to fibers with optical connections to detectors. Borsboom shows only combinations of emitters and detectors in the core. Assertion that this claim is obvious over the combination of art would require that there be a teaching to alter the fundamental nature of the arrangement of emitter fibers and collector fibers in the core. There is again no basis for such an assertion on the record. In fact, eliminating the combination of emitters and detectors in the core would destroy the functionality of measuring opaque materials that is an objective of Borsboom. There is no reason from any reference used in the rejection to so fundamentally alter the structure of Borsboom. Even without the assertions of Applicant as to the benefits of such an altered construction, the simple fact is that this structure *is not obvious from the teachings of the references in this rejection*. There is no assertion on the record and no teaching pointed to on the record that would support a rejection under 35 U.S.C. 103 against the limitations in this claim.

The exact same arguments hold true for all claims dependent from claim 57 (claims 58, 59, 60, 61 [dependent from 59], 62 [dependent from claim 61] and 63. There is no teaching which would motivate one ordinarily skilled in the art to modify the article described in the specification or that taught by Borsboom to have the features recited in these claims (57-63). Hirao et al. have no teaching at all with respect to the distribution of emitting optical fibers around a core of only collecting optical fibers, as that reference does not have, nor has been asserted to have, concentric distributions of any fibers.

Patentability of Claims 1 and 7

As recognized by the Examiner, Borsboom discloses only a single path through the sample, whereas Applicant recites "...a plurality of different transmission paths...defining each of said paths by corresponding and separated surface areas on said materials." (Emphasis added). Borsboom's second path is not characterized by separated surface areas but rather by intermixed emitters and detectors. As noted above, this configuration is essential to Borsboom's objective of measuring opaque objects.

Claims 1 and 7 recite that "...at least one of said surface areas of each of said paths being extended in length at substantially constant spacing from the other surface..." The distribution shown by Borsboom only supports a teaching of a random or ordered distribution of optical emitters and collectors in the center of the sensor head. The mere fact of distribution of optical emitters and detectors in the core (rather than a single emitter or a single detector) prevents this limitation from being met for Borsboom's second path.

From Borsboom's teaching it can be determined that the preferred diameter D of the central fiber is approximately equal to or larger than twice the radial distance s (column 2 line 66 to col 3 line 3). Because the emitters are distributed in an area with dimensions

that are significant with respect to diameter of the concentric circle of collectors , the central surface area of each of the paths will not be at substantially constant spacing from the other surface area. Looking at Figure 4, where the Office Action asserts a concentric distribution of optical fibers, it can be readily seen that the spacing between the central emitting fibers 3 and the exterior fibers 7, even if they were only collecting fibers, is not at substantially constant spacing. The spacing between the central fibers and exterior fibers is clearly eccentric, depending upon the position of the central fibers within the core. Neither the teachings in the specification, Borsboom, Howarth or Hirao et al. teach that this type of spacing specifically shown by Borsboom should be eliminated. Without such a teaching, the claim is unobvious from the teachings of these references. There is no teaching of "...at least one of said surface areas of each of said paths being extended in length at substantially constant spacing from the other surface area..." Without such a specific teaching in the art, the claim can not be asserted to be obvious.

Additionally, Applicant claims "...the total length of said extended surface area of said each of said paths being substantially greater than the mean distance separating said corresponding and separated surface areas defining each of said paths;" Borsboom states that "...the apparatus according to the invention is characterized in that in said sensor head, at least one solid optical illuminating fibre and at least one juxtaposed optical detection fibre are disposed with their optical axes parallel to each other..." (Column 2, lines 25-29). One juxtaposed optical detection fiber cannot form "the extended surface area" of Applicant's claim. Borsboom has no teaching concerning the advantages of using a plurality of optical detection fibers arranged in a ring. Neither Howarth nor Hirao teach the use of extended surface areas for illumination or detection. Howarth shows (Figure 7) that his two detectors are typically oriented in the direction of flow of the material in a pipe spaced 1" and 3" from the source (Figure 6 and column 5, lines 1-4). He also states that "...mounting of the gauge of the present invention on a pipeline carrying pulp ... may be relatively difficult. This is especially true when the pipe diameter is relatively small or relatively large;..." These difficulties argue against the use of extended surface areas "...substantially greater than the mean distance separating said ... surface areas defining each of said paths;" which would only increase the difficulty. Hirao (column 2, lines 43-45 and 60-62) specifically teaches "...a plurality of irradiating points which are disposed in substantially the same direction with respect to the light receiving point..."(emphasis added) which is contrary to the structure of Borsboom and teaches away from rings or other extended source or detector areas. This is another specific limitation in the claims which is not specifically taught or suggested by the references. To that end, this limitation is another aspect of the unobvious subject matter of the invention as claimed.

The prior art of two paths disclosed in the specification, is as stated, applicable only to clear materials.

Claims 1 and 7 now specifically recite that each of the signals received by the sensing means comprises a spectrum, that is by definition multiple wavelengths (cf. Webster's Seventh New Collegiate Dictionary). Borsboom clearly describes the use of "...a

monochromator or a colour or interference filter 16... depending on the use of the apparatus or on the absorption characteristics to be investigated, for example, translucent material.” (Column 5, lines 6-9). Each of these devices provides only a single measurement wavelength, and this is further supported by the later description that “...in the case of measurements with regard to meat...an interference filter is used with a transmission at 560nm...” (Column 5, lines 9-13). Borsboom, in addition to teaching only monochromatic devices, does not provide any positive indication that multiple wavelengths are useful for translucent materials as in the practice of the invention claimed by Applicant in this Application. Similarly, Howarth teaches the use of a common wavelength in that part of the specification applicable to the description of Figures 6 and 7 (e.g., column 5, lines 1-9) which was referenced by the Examiner. As Howarth clearly shows a single “common” wavelength, the combination of Borsboom and Howarth fails to show any device with multiple wavelengths as described with the use of a spectrum as recited in claims 1 and 7. No single wavelength can differentiate between a plurality of analytes and interferences as enabled by the practice of the invention claimed by Applicant in claims 1 and 7. The additional features now in claims 1 and 7 further provide recitations of unobvious subject matter between the claimed invention of claims 1 and 7 and the combination of Borsboom and Howarth.

Furthermore, the claims now recite “...from a spectrum related to the analytes and interferences within said material...”. Although Hirao teaches use of three wavelengths, they are all related to the analytes Hb and HbO₂ and thence to oxygen saturation. Hirao has no teaching of utilizing the spectral information of interferences.

The claims have been further amended to specify “processing and combining said signals in accordance with appropriate chemometric modeling techniques and determination of model parameters during the calibration process...”. Borsboom does not teach combining the signal from the central fiber with that of the parallel juxtaposed fibers. In the case of opaque materials, “the parallel juxtaposed fibres 7 will receive no reflected light.” (column 5 lines 32-33). Borsboom’s calibration process for translucent materials involves two steps, first measuring “(deflection of the signal from the central fiber)” (column 5 lines 60-61) and separately “...the deflection of the detector at the parallel juxtaposed fibres...” (Column 5 lines 65-67). He clearly uses these signals separately, the first for scattering and the second for absorption measurements. He does not teach any form of chemometric modeling or determination of model parameters during the calibration process.

As partially referenced by the Examiner, Borsboom suggests “The position of the optical fibers within the sensor head relative to each other that is optimal for absorption depends on the nature of the material to be investigated and, if desired, is determined by experimentation. For this purpose, a sensor head could be made in which a large number of juxtaposed fibers of diameter d is arranged concentrically around a central optical fiber with an increasing radius. Measurements made with such a sensor head gives a good picture of the amount of reflected light that has entered the fibres arranged concentrically in rings, and hence the light reflection as a function of distance from the light beamed

into the material being investigated.” In other words, of the optimal optical construction. Borsboom does not combine the signals from the different rings as is now claimed in claims 1 and 7. Borsboom simply uses different rings, one at a time, to determine the optimal spacing of his juxtaposed detection fibre(s).

Howarth does disclose the use of the ratio of the signals at a single wavelength from two detectors spaced at different distances from a single source to measure consistency. A simple ratio of two signals at one wavelength does not comprise “chemometric modeling” as now recited in claims 1 and 7. Chemometric modeling requires multivariate, i.e., multi-wavelength calibration. Hirao teaches a specific deterministic set of equations for processing and combining the measurements at three wavelengths to determine Hb, HbO₂, and oxygen saturation. There is no teaching of chemometric modeling or a calibration process.

Patentability of Claims 7 and 33 (and Claims Dependent Thereon)

Claim 7 is patentable for the same reasons as claim 1 identified above, except that the recitation is even more restrictive and delimiting from those recited in claim 1. Claim 7 requires that

“...at least one of said surface areas of each of said transmission paths being...substantially constantly spaced from its corresponding surface area.”

Without any teaching or inherent existence of this limitation, the combination of references can not sustain a rejection under 35 U.S.C. 103.

Patentability of Claim 6

The amendment to claim 6 clearly recites the directionality of the radiation at the surface of the material. Borsboom specifically teaches “...at least one solid illuminating fibre and at least one juxtaposed optical detection fibre are disposed with their optical axes parallel to each other...” (Column 2, lines 26-29). The angle of bevel referred to by Borsboom (column 3, lines 47-50) provides refraction in only one direction, thereby maintaining parallel optical axes, and not “...generally toward the said corresponding and separated surface area on said material.”

Howarth shows in Figure 4 that detectors are mounted at an angle and discloses (column 3, lines 64-67) that “Receiver portion 14 includes two detectors; one for the reference wavelength and the other for the sample wavelength which are coupled to the common window 18 through the aperture 48 as best illustrated in FIG. 4.” The angling of the detectors is done to allow use of a common window, not to provide optical directionality at the surface of the material. Howarth continues (at Column 4, lines 7-11) “As is apparent from examination of the surface of window 18 in FIG. 3, this diffusion window provides a solid half angle of reradiation so that the detectors which are angled through holes 51 and 52 are fully sensitive to such radiation.” While window 18 does not appear in Figure 3, the meaning of this description is quite clear. Window 18 is intended to destroy directionality by providing a solid half angle of radiation, i.e., full diffusion. This is reinforced by Howarth (column 2, lines 49-55). The windows 17 and 18 are preferably of translucent quartz to provide in the case of transmission window 17

full diffusion of the source radiation into material **16** as shown at **19** and in the case of receive window **18** a solid half angle of received radiation which is detected by a sample radiation detector **21** and a reference detector **22**." Full optical diffusion, as described in the construction of Howarth, destroys the directionality of the radiation.

It is absolutely clear that neither Borsboom nor Howarth teaches the use of directionality of the illumination or the received radiation as recited in claim 6 by Applicant.

Patentability of Claims 33 and 36 (and Claims Dependent Thereon)

In addition to the reasons for patentability asserted for claims 1 and 7 above, claims 33 and 36 recite the additional limitation that

"...an extended surface area of one of said paths being contained within the boundary defined by an extended surface area of another of said paths and being substantially surrounded by the extended surface area of said another of said paths."

These limitations are not shown in any combination of the art cited in the rejection against claim 36. Without any teaching or inherent existence of this limitation, the combination of references can not sustain a rejection under 35 U.S.C. 103.

Without a clear basis for that assertion, in addition to a showing of the obviousness of the other structural differences in the apparatus, claim 36 is clearly patentable.

Removal of Hirao et al. As a Reference

Accompanying this response is a declaration under 37 C.F.R. 1.131 by the inventor, Mr. Edward W. Stark, which removes the Hirao et al. reference as prior art against the present invention. To whatever degree that reference was essential to the present rejection, the rejection is additionally weakened and must fail.

The accompanying declaration states the following:

1) That all of the documents which were used to establish conception of the invention prior to December 15, 1989 were in the physical possession of Mr. Stark within the United States prior to December 15, 1989. That all sets of documents used to show conception of the invention prior to December 15, 1989 have dates thereon which were made contemporaneously with the documents and that all of these dates are earlier than December 15, 1989, except for the nine sets of handmade notes, as stated in the declaration.

2) That the documents clearly describe the substance invention of the claimed subject matter of, for example, claim 1 as presently pending (including amendments submitted herewith).

3) Document 1 from Fostec to Mr. Edward Stark shows the use of concentric rings of fiber optics for illumination interspersed with rings for detection surrounding a fiber optic detection core,

4) Document 2 from Volpi Manufacturing USA shows a quotation for fiber optic

materials to be used in the construction of a device within the scope of the invention recited in claim 1 of the application (as amended).

5) Based on a regular stream of documents relating to development of associated diode-array spectrometric equipment, ordering of supplies, negotiating agreements for the construction and development of spectrometric equipment, and the like, especially with indications from the supplier that the time of delivery of parts when ordered takes about six weeks (note Fostec quotation of February 19, 1990), Applicant has shown such regular and continuing conduct and effort which establishes diligence in the reduction to practice of the invention after clear written documentation of conception of the invention prior to December 15, 1989.

6) That the invention was reduced to practice from the ordered materials in a manner which showed due diligence from conception of the invention to said first reduction to practice in August of 1990.

The accompanying declaration thereby shows such facts supported by character and weight which establish conception of the invention within the United States prior to December 15, 1989 and diligence from that date to actual reduction to practice. Hirao et al. has therefore been removed as a reference in this application against the subject matter represented by the pending claims and their equivalents.

Ineffectiveness of Howarth As a Teaching of Multiple Paths

Howarth will not sustain the rejection presented against the claims by itself in combination with the prior art described in the specification and Borsboom because the requirements for spacing between the sources and receivers are physically incompatible. Borsboom teaches "...the diameter D is approximately equal to or larger than four times the inverse of the scattering coefficient of the material to be investigated, the radial distance s is in the order of twice the inverse of the scattering coefficient..." (Column 2 line 67 to column 3 line 3). For biological materials "... the sensor head can be based on a fixed configuration, that is to say, a central optical fiber with diameter D=2 mm; a distance s of about 1 mm;" (Column 6 lines lines 27-30). He also states that for opaque materials "...at a diameter D of 5 mm, the apparatus will function as a true reflectometer." Howarth (Figure 6 and column 5 lines 1-4) teaches that the receiving windows should be spaced at 1" and 3" from the source to obtain a linear ratio for determination of consistency.

Howarth also has a single emitter and multiple collectors, the same deficiency noted in Borsboom. Howarth therefore can not correct the deficiencies of Borsboom and the prior art in the specification, but adds further complexity that must be overcome in attempting to find a teaching of the present invention.

Ineffectiveness of Hirao et al. As a Teaching of Multiple Paths

Although Hirao et al has been removed as a reference, even if it were not removed, there is still an ineffective teaching available for the purposes of sustaining a rejection under 35 U.S.C. 103 also because of the physical incompatibility of the spacing criteria. Hirao teaches (figure 3) that a specific minimum distance L_0 is required to obtain a substantially linear relationship between the log of the distance L and the log of the received power P. This relationship is essential to the specific calculation method of Hirao. Hirao teaches from the data of Figure 6 that "It is therefore required that the distance between the light irradiation point and the light receiving point is at least 3 cm or more, and preferably, 4 cm or more." Such a spacing is contrary to Borsboom's teaching of a spacing s of at most a few millimeters discussed above.

Although Hirao is somewhat better than Howarth in allowing for multiple emitters, there is still no teaching of the requirement that a

"...said surface areas of each of said paths being...at substantially constant spacing from the other surface area of each of said paths..."

Without some basis for a clear teaching of that limitation, the reference fails to correct all of the deficiencies of the prior art in the specification and Borsboom.

All rejections and issues have been specifically addressed and are believed to have been overcome by these amendments and remarks. It is earnestly believed that all claims should be allowed and the rejections of record withdrawn.

The Examiner is hereby authorized to charge **Deposit Account no.19-0743** for the Petition for Extension of Time and the fee for the added claims. The Examiner is invited to contact the Applicant's Attorney at the below-listed telephone number if there are any questions regarding this communication.

Respectfully submitted,

By Applicants' Attorneys,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231 on January 14, 1998.

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